

**REMARKS**

Claims 1, 3-22, 37, 38, 43-45, 66, 84-88, 108 and 119-132 were pending in the application. Claims 84-88, 108, and 119-126 were pending and withdrawn. Claims 2, 15, 16, 23-36, 39-42, 46-65, 67-83, 89-107, 109-118 and 127 have been canceled. Claims 1, 3, 9, 17-20, 37, 119, 123, 124 and 128 have been amended. Of the pending and withdrawn claims, claims 119, 123 and 124 have been amended. Claims 133-135 have been added, and are withdrawn. Accordingly, upon entry of the amendments presented herein, claims 1, 3-14, 17-22, 37, 38, 43-45, 66, 84-88, 108, and 119-135 will be pending, of which claims 84-88, 108, 119-126, and 133-135 will be pending and withdrawn.

Claims 1, 3, 9, and 17-20 have been amended by the removal of substituent definitions. Claims 37, 119, 123, 124 and 128 have been amended to reassign dependencies. Newly added and withdrawn claims 133-135 are dependent on currently pending and withdrawn claims 119, 123 and 124, respectively.

No new matter has been added.

The foregoing claim amendments have been made solely for the purpose of expediting prosecution of the present application and should in no way be construed as acquiescence to any of the Examiner's rejections in this or in any other Office Action issued in the present application. Applicants reserve the right to pursue the subject matter of the present claims prior to being amended herein in this application or in another related application.

In view of the foregoing claim amendments and the arguments set forth below, Applicants respectfully submit that the claims are now in condition for allowance.

***Double Patenting***

Claims 1, 3-22, 43 and 66 have been rejected provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 10 of copending U.S. Patent Application No. 10/657,910 ("the '910 application"). In response, Applicants note that both the instant application and the '910 application claim the benefit under 35 U.S.C. § 120 of international application PCT/US03/07377 ("the '377 application"), filed March 7, 2003. Whereas the instant application is the 35 U.S.C. § 371 national phase entry of the '377 application, the '910 application is a continuation-in-part of the '377 application. Moreover,

Applicants note that according to MPEP § 804(I)(B)(1), “[i]f both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.”

Applicants respectfully submit for the Examiner’s consideration that the instant application claims the base invention, whereas the ‘910 application claims the improvement insofar as it includes claims with the added limitation “systemic administration.” Moreover, a terminal disclaimer over the instant application was filed during prosecution of the ‘910 application on May 7, 2009. Therefore, it is appropriate to withdraw the outstanding double patenting rejection of the instant application.

Accordingly, Applicants respectfully request that the obviousness-type double patenting rejection be reconsidered and withdrawn.

### ***Rejoinder of Claims***

Upon a finding of allowability of claims 1, 3-22, 37, 38, 43-45, 66, 84-88, 108 and 119-132, Applicants seek rejoinder of currently pending and withdrawn claims 84-88, 108, and 119-126, as well as newly added and withdrawn claims 133-135. Applicants note that these method claims depend from compound claims 1, 3, 131 and 132. See MPEP § 821.04.

**CONCLUSION**

In view of the foregoing, entry of the amendments and remarks herein, reconsideration and withdrawal of all rejections, and allowance of the instant application with all pending claims are respectfully solicited. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

An extension of time and appropriate fee is being filed herewith. If any additional fees are due, please charge our Deposit Account No. 12-0080, under Order No. EISN-018US from which the undersigned is authorized to draw.

Dated: October 23, 2009

Respectfully submitted,

Electronic signature: /Brian C. Trinqué, Ph.D./  
Brian C. Trinqué, Ph.D.  
Registration No. 56,593  
LAHIVE & COCKFIELD, LLP  
One Post Office Square  
Boston, Massachusetts 02109-2127  
(617) 227-7400  
(617) 742-4214 (Fax)  
Attorney/Agent For Applicant